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EXAMINER	
PRICKRIL, B	
ART UNIT	**PAPER NUMBER**
1817	7

DATE MAILED: 06/13/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 3/28/97 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474..
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1-42 are pending in the application.
   Of the above, claims 1-26 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 27-42 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group III, claims 27 to 42 is acknowledged. Claims 1-26 are withdrawn from consideration as being drawn to nonelected inventions.

Claim Rejections

2. Claims 27-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-39 are drawn to vaccine compositions against "a case of disease caused by infection by *B. pertussis*". The art recognizes *B. pertussis* as the causative agent of pertussis, but does not recognize this organism to be the causative agent of other diseases. Therefore it is unclear whether the claimed vaccine compositions are intended to protect against only pertussis or whether other unspecified diseases are intended.

Claim 40 is drawn to the genus *Bordetella*, while the disclosure is clearly directed to *B. pertussis*, the causative agent of pertussis. It is unclear whether applicants intend to include a broad genus encompassing hundreds of species, or to recite only *B. pertussis* in keeping with the overall disclosure

The term "selected relative amounts"is vague and fails to adequately circumscribe what is being claimed. The components are either present in a stated ratio (i.e., relative amounts) or they

are not; therefore it is unclear what "selected" refers to. Although not stated as such in the claims, this terminology would reasonably be interpreted by the artisan to refer to acellular vaccines, and therefore this interpretation is assumed for purposes of this Office action.

The term "about" is used consistently in the claims when any numeric parameter is cited. It is unclear what limits are intended by the use of this term because the limitations on the specified parameter will be interpreted differently by different individuals. For example, does this term include 65% (50%?) when referring to "at least about 70%" in claim 27? Another example occurs in claim 35 where "about 2:1" can easily be interpreted as "1.5:1" and vice versa. It is therefore unclear what is being claimed.

The term "immunoeffective amount" in claim 40 is indefinite. This term appears to encompass any effect whatsoever on the immune system, and is not apparently limited to immunization. For example, an "immunoeffective amount" of an "immunogenic composition" is reasonably interpreted to include the mere production of antibodies - or other effect related to the immune system - without any nexus whatsoever to producing immunity. It is unclear what scope of effectiveness is intended by this terminology.

The claims address amounts of various components as nitrogen equivalents. For example, claim 29 refers to "about 10 ug nitrogen of pertussis toxoid". In this example it is unclear what is meant by "nitrogen of pertussis toxoid", and in the larger sense it is unclear how the apparent nitrogen equivalent is determined such that the artisan could determine what amounts of the various vaccine components are present. Because the disclosure provides

inadequate guidance with respect to determination of nitrogen values, and in order to expedite prosecution, it is assumed that the amounts of components recited as "nitrogen" are identical to the actual amount of that component. Thus, for example, "about 10 ug nitrogen of pertussis toxoid" of claim 29 is interpreted to mean "10 ug of pertussis toxoid". Appropriate correction or clarification is required.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 27-29, 31-34 and 38-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Englund et al. [*J. Infectious Dis.* **166**, 1436-1441 (1992); art of record].

Englund et al. disclose an acellular pertussis vaccine used in a controlled study in adults and young children (see abstract). The vaccine is identical to that claimed by applicants, is highly effective, and is used in a method of immunizing a human host against pertussis.

5. Claims 27, 34, and 38-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cherry [*Vaccine* **10**, 1033-1038 (1992)].

Cherry discloses a pertussis vaccine which is identical to applicant's vaccine formulation. See, for example, the third entry in Table 2 on page 1036. The vaccine of Cherry was found to be effective in treating pertussis in human subjects.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 27-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Englund et al. [*J. Infectious Dis.* **166**, 1436-1441 (1992); art of record] or Cherry [*Vaccine* **10**, 1033-1038 (1992)].

Englund et al. and Cherry disclose acellular pertussis vaccines which are identical to the vaccines of applicants, as recited. Englund et al. and Cherry et al. do not disclose amounts of all purified components or ratios as stated in applicant's claims. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the vaccines of Englund et al. or Cherry either contained the component concentrations claimed by applicants based on the ordinary level of skill in the art, or that the component concentrations should be adjusted such that applicant's invention was rendered obvious. Motivation to use the component concentrations recited by applicants is provided by the expectation that adjustment of these concentrations would provide advantages which are well known such as a decrease in the level of adverse reaction to the vaccine. Acellular pertussis vaccines containing the same components as claimed by applicants were in clinical trials at the time applicant's application was filed, and based on this knowledge and the prior existence of many related pertussis vaccines, the artisan would have had ample motivation to adjust component concentrations, when necessary, in order to obtain those recited by applicants in order to minimize side effects or increase efficacy.

8. No claims are allowed.

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benet Prickril, Ph.D., whose telephone number is (703) 305-5933. The examiner normally can be reached Monday through Thursday between 7:30 AM and 5:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D., can be reached at (703)308-4310. The fax phone number for Art Unit 1817 is (703) 305-7939.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marian C Knode

Benet Prickril, Ph.D.
March 28, 1997

MARIAN C. KNODE
SUPERVISORY PATENT EXAMINER
GROUP 1800